

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. The compound or composition of general formula I, according to Claims 1, 3-9, wherein W is a phenyl ring, m is 0 and n is 0.
- II. The compound or composition of general formula I, according to Claims 1, 3-9, wherein W is a phenyl ring, m is 0 and n is 1.
- III. The compound or composition of general formula I, according to Claims 1-9, wherein W is a phenyl ring, m is 1 and n is 0.
- IV. The compound or composition of general formula I, according to Claims 1, 3-5, 7, 9, wherein W is a heteroaryl ring containing at least 2 heteroatoms, wherein at least one heteroatom is nitrogen, m is 0 and n is 0.
- V. The compound or composition of general formula I, according to Claims 1, 3-5, 7, 9, wherein W is a heteroaryl ring containing at least 2 heteroatoms, wherein at least one heteroatom is nitrogen, m is 0 and n is 1.

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- VI. The compound or composition of general formula I, according to Claims 1-5, 7, 9, wherein W is a heteroaryl ring containing at least 2 heteroatoms, wherein at least one heteroatom is nitrogen, m is 1 and n is 0.
- VII. The compound or composition of general formula I, according to Claims 1, 3-5, 7-9, wherein W is a heteroaryl ring containing only 1 nitrogen atom, m is 0 and n is 0.
- VIII. The compound or composition of general formula I, according to Claims 1, 3-5, 7-9, wherein W is a heteroaryl ring containing only 1 nitrogen atom, m is 0 and n is 1.
- IX. The compound or composition of general formula I, according to Claims 1-5, 7-9, wherein W is a heteroaryl ring containing only 1 nitrogen atom, m is 1 and n is 0.
- X. The compound or composition of general formula I, according to Claims 1-9, which are not covered in Groups I-IX.
- XI-XX. A method for treating or prophylaxis of a disease, according to Claim 10, by administering a compound or composition wherein the compound or composition is from Groups I-X.

2. Claims 11 and 12 provides for the use of a compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it

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merely recites a use without any active, positive steps delimiting how this use is actually practiced. These claims are hereby withdrawn.

The inventions listed as Groups I - X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking the claims is a compound of general formula I. In the instant case Groups I-X are directed to structurally dissimilar compositions such that the variable core created by varying the definitions of the Formula (I) do not belong to a recognized class of chemical compounds in the art, and references that exist in anticipating one invention would not render obvious the others. For example, a 4-phenyl-1,2,3,6-tetrahydropyridine core is different from a 7-(1,3,5-triazin-2-yl)-3,9-diazabicyclo[3.3.1]non-6-ene core. Thus, separate searches in the literature would be required. Each group's compounds are made and used independently of each other and could support separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structures as functional equivalents of each other. The mere fact that there is a single similarity is not in itself a significant reason to render the whole embodiment obvious. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Therefore the feature linking the claims does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the art.

Accordingly, Groups I – X are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

3. This application contains claims directed to the following patentably distinct species the compounds of Claim 8, the diseases of claims 9 and 10. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1 and 10 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

5. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after

the election, applicant must indicate which of these claims are readable on the elected invention.

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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon.-Thurs. 7:30-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H Murray/
Patent Examiner
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**/James O. Wilson/
Supervisory Patent Examiner
Art Unit 1624**

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a) The various structures and forms of the compound or composition of formula I.

- b) The various methods of use for compounds or compositions of formula I.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. The claims are deemed to correspond to the species listed above in the following manner:

The claims represent the various structures and forms of the compound or composition of formula I.

The following claim(s) are generic: Claim 1.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The inventions listed as Groups I-XXVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-X lack unity with Groups XI-XXVII because Groups I-X are directed towards a compound, whereas Groups XI-XXVII are directed towards a method of using the compounds or compositions for the treatment or prevention of a disease associated with dysregulation of the rennin-angiotensin system (RAS).

Groups I-X lack unity with each other as well. Groups I-X follow the general formula I, however, the formula is so broad between each of Groups I-X and also within each individual Group so as to not have a common core. Groups I-X are defined as a compound of general Formula I, which comprises of m and n moiety where m and n can both be either 0 or 1, so long as they are both not 1. This results in three different bicyclic ring systems that can be formed where: 1) m and n =0; 2) m=1 and n=0; or 3) m=0 and n=1. Groups I-X are also defined as a compound of general Formula I, which comprises of an X and W moiety that may be -CH- or a N. This results in three different possibilities: a phenyl, pyridyl, or pyrimidinyl ring directly attached to the bicyclic ring system. A common core is important aspect in defining a single general inventive concept. The international application shall relate to one invention only or to a group of inventions so linked as to form a general inventive concept under PCT Rule 13.

Groups XI-XXVII also lack unity, as they are method Groups drawn to specific compound or composition claims. Groups XI-XX are method Groups drawn to a compound or composition from claims 1-7 for treating or preventing a disease, with numerous diseases listed, associated with dysregulation of the rennin-angiotensin system (RAS). Whereas Group XXI-XXVII are method Groups drawn to a compound or

composition from claim 8 for treating or preventing a disease, with numerous diseases listed, associated with dysregulation of the rennin-angiotensin system (RAS).

5. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is (571) 272-9023. The examiner can normally be reached on M-F 7:30-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Jeffrey H. Murray